

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

TALECRIS BIOTHERAPEUTICS, INC., AND)
BAYER HEALTHCARE LLC,)

Plaintiffs,)

v.)

C.A. NO. 05-349-GMS

BAXTER INTERNATIONAL INC., AND)
BAXTER HEALTHCARE CORPORATION,)

Jury Trial Demanded

Defendants.)

REDACTED VERSION DI 254

BAXTER HEALTHCARE CORPORATION,)

Counterclaimant,)

v.)

TALECRIS BIOTHERAPEUTICS, INC., and)
BAYER HEALTHCARE LLC,)

Counterdefendants.)

**PLAINTIFFS' MEMORANDUM OF LAW IN SUPPORT OF THEIR
MOTION *IN LIMINE* NO. 1 TO PRECLUDE BAXTER FROM
PRESENTING TESTIMONY REGARDING ALLEGED "DESIGN AROUNDS"**

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INTRODUCTION

Plaintiffs Talecris Biotherapeutics, Inc. and Bayer Healthcare LLC (“Plaintiffs”) move *in limine*, under Fed. R. Civ. P. 37(c)(1) and F.R.E. 702, to preclude Defendants Baxter International Inc. and Baxter Healthcare Corporation (“Baxter”) from introducing testimony of an alleged “design around”. For the first time in a January 31, 2007 report of its damages expert, R. Bruce Den Uyl, Baxter refers to an alleged “design around”,

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Mr. Den Uyl identified as the sole source of his opinion a Baxter employee, Mr. Richard Schiff, who was not previously identified as having knowledge relevant in this case and was never deposed, and Baxter’s non-infringement expert, Dr. Terrance Snape. Baxter should not be permitted to assert for the first time a design-around theory in an expert report where there are no facts in the record to support it. There is also no reliable evidence that the alleged design around is both acceptable and available, as uniformly required by the case law. It is entirely improper to use a technically unqualified damage expert to first attempt to introduce technical facts into the record, and then to render a damage opinion based on them.

Mr. Den Uyl stated in his expert report and deposition that his opinions concerning the alleged design around, including whether it would be “acceptable”, “feasible for Baxter” and would not infringe the ‘191 patent, were based solely on his oral conversations with Mr. Schiff and Dr. Snape. (Mason Dec.¹ Ex. 2. at 18:17-19:8; 26:10-13; 28:3-12; 91:14-18.) Mr. Schiff was never identified by Baxter as possessing any information relevant to this case, and Baxter never disclosed its design-around theory in discovery. (See Mason Dec. Exs. 3-5.) Similarly, in his

¹ The “Mason Dec.” is the Declaration of Jaclyn M. Mason in Support of Plaintiffs’ Motions in Limine Nos. 1-5, filed concurrently herewith.

deposition, Mr. Den Uyl stated that two members of his staff had one conversation with Dr. Snape, but Mr. Den Uyl did not personally have any conversations with Dr. Snape. (Mason Dec. Ex. 2 at 91:2-12; 122:2-16). During his deposition, however, Dr. Snape directly contradicted Mr. Den Uyl. He testified that the very basis of the alleged design around –

(Mason Dec. Ex. 6 at 151:10-152:10),

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(*id.* at 153:8-154:3).

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(*Id.* at 152:11-22.)

When Mr. Den Uyl was asked about his understanding of the alleged design around,

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(*See generally* Mason Dec. Ex. 2 at 19-25.)

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(*id.* at 19:21-25);

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(*id.* at 20:1-8);

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(*id.* at 20:16-20);

REDACTED

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(*id.* at 22:21-25).

(*id.* at 19:9-20),

REDACTED

REDACTED

(*id.* at 26:23-25

(*id.* at 23:8-10).

REDACTED

REDACTED

(*id.* at 25:5-7),

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(*id.* at 26:23-25).

LEGAL STANDARDS AND ARGUMENT

1. Mr. Den Uyl's Testimony Should Be Excluded Under Rule 37(c)(1)²

To the extent Mr. Den Uyl's opinion is based on oral conversations he had with Mr. Schiff, Mr. Schiff was never listed on Baxter's initial or supplemental disclosures or otherwise identified as an individual with relevant knowledge in this case, *see* Fed. R. Civ. P. 26(a)(1), and he was therefore never deposed. Plaintiffs should not now be ambushed by an expert opinion based exclusively on new and previously undisclosed "factual" information. The opinion should be precluded on this basis alone. *See Dey, L.P. v. Ivax Pharmaceuticals, Inc.*, 233 F.R.D. 567, 573 (C.D. Cal. 2005) (finding expert testimony based on facts not available to the public and not disclosed during fact discovery in the case improper).

2. Mr. Den Uyl's Testimony Is Also Inadmissible Under F.R.E. 702

Mr. Den Uyl's opinions are inadmissible because they are irrelevant and unreliable pursuant to Federal Rule of Evidence 702 which provides:

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training or education, may testify thereto in the form of an opinion or otherwise, if **(1) the testimony is based upon sufficient facts or data**, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

Fed. R. Evid. 702 (emphasis added). Under Rule 702, this Court acts as a "gatekeeper" through a preliminary determination that the proffered evidence is both relevant and reliable. *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 147-49 (1999).

² "A party that without substantial justification fails to disclose information required by Rule 26(a) or 26(e)(1), or to amend a prior response to discovery...is not...permitted to use as evidence at trial any witness or information not so disclosed." Fed. R. Civ. P. 37(c)(1).

A design around must be both “available” and “acceptable”. *Grain Processing Corp. v. American Maize-Products Co.*, 185 F.3d 1341, 1346-49 (Fed. Cir. 1999). To be “acceptable”, the substitute product or process must have the advantages of the patented one. *See Standard Havens Prods. v. Gencor Indus., Inc.*, 953 F.2d 1360, 1373 (Fed. Cir. 1991) (“A product on the market which lacks the advantages of the patented product can hardly be termed a substitute acceptable to the customer who wants those advantages.”). The process must also have been “available” at the time of the hypothetical negotiation – there must be record evidence that the infringer “had all of the necessary equipment, know-how, and experience” to make the alleged design around. *See id.* at 1354; *Micro Chem., Inc. v. Lextron, Inc.*, 318 F.3d 1119, 1123 (Fed. Cir. 2003) (discussing *Grain Processing* in the context of a reasonable royalty analysis). Switching to a design around after this period does not show availability of the design around at this critical time. *See Grain Processing*, 185 F.3d at 1353.

Mr. Den Uyl was unable to identify any reliable factual basis to support his opinion. His opinion about the feasibility, timing, and costs of the design around is based on undocumented, oral conversations with Dr. Snape and Mr. Schiff. Mr. Schiff was not identified during fact discovery, and there are no supporting documents. Dr. Snape testified in his deposition that

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See supra at 1-2.

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then how can Mr. Den Uyl

(an admitted non-technical expert) be permitted to testify about it?

Additionally, there is no indication that Mr. Schiff or Dr. Snape even attempted to determine whether the design around would be “acceptable” and “available”. Mr. Den Uyl could

not identify any facts supporting either prerequisite. Mr. Den Uyl should not be permitted to opine about the impact of a supposed design around when: (1) he is admittedly not a technical expert; (2) he does not know whether

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and (3) he does not know what the effect of the design around is on the functionality, safety, and characteristics of the product or whether it would even obtain FDA approval. Mr. Den Uyl failed to set forth any factual basis as to whether the product made by the modified process would have the advantages of the patented process.

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And, Mr. Den Uyl identified no evidence that the alleged design around was “available” at the time of infringement –

(Mason Dec. Ex. 2 at 141:5-10; *see also Grain Processing*, 185 F. 3d at 1346-9.) There is no evidence of record, and Mr. Den Uyl could not point to any evidence, that Baxter possessed all of the necessary equipment, know-how and experience at the time of the hypothetical negotiation

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In short, Mr. Den Uyl’s belatedly contrived opinion does not have the factual support to make it reliable (or even relevant) to the issues to be presented to the jury.

CONCLUSION

Because testimony regarding the alleged design around is inadmissible under Fed. R. Civ. P 37(c)(1) and Fed. R. Evid. 702, Plaintiffs respectfully request that the Court grant its motion *in limine* to exclude all such testimony at trial.

Respectfully submitted,

/s/ Jeffrey B. Bove

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CERTIFICATE OF SERVICE

I hereby certify on this 23rd day of April, 2007 I electronically filed the foregoing **Plaintiffs' Memorandum of Law in Support of Their Motion *In Limine* No. 1 to Preclude Baxter From Presenting Testimony Regarding Alleged "Design Arounds"** with the Clerk of Court using CM/ECF which will send notification of such filing to the following:

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I also hereby certify that a true copy of the foregoing document was served upon the following in the manner indicated on April 23, 2007.

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